

REMARKS

Claims 2, 3, 12 and 14-22 are pending. No new matter has been added.

Objection to Priority

The Examiner asserts that "Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120." Specifically, the Examiner states that "an application in which the benefits of an earlier filed application are desired must contain specific reference to the prior application(s) in the first sentence of the specification."

A petition under 37 CFR 1.78(a)(3) and the surcharge set forth in 37 CFR 1.17(t) are being submitted herewith.

Obviousness-type Double Patenting

Claims 2, 3, 5, 12 and 14-21 are rejected "under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1, 8-11, 14-21, 24, 31 and 32-34 of U.S. Patent No. 6,248,360." According to the Office Action, "although the conflicting claims are not identical, they are not specifically distinct from each other." Specifically, the Office Action states that:

[I]t is noted that the '360 patent does not specifically claim a pharmaceutical composition that comprises an adsorption [sic] enhancer. However, several of the examples of the claimed subject matter in the patent discloses compositions comprising capmul Because the specification of the prior patent discloses embodiments comprising the enhancer, this constitutes an obvious variation of the claimed composition.

The Office Action also includes an excerpt from the MPEP section 804, and concludes that:

the courts have held it permissible to use the specification in determining what is included in, and obvious from, the invention defined by the claim on which the rejection is based. This is true even where elements drawn from the specification describing the claimed invention which are not elements in the claim itself.

Applicants respectfully traverse this rejection as contrary to well-established law. The Court of Appeals for the Federal Circuit "precedent makes clear that the disclosure of a patent cited in support of a double patenting rejection cannot be used as though it were prior art, even where the disclosure is found in the claims." *General Foods Corp. v. Studeinggesellschaft Kohle mbH*, 972 F.2d 1272, 1281, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992). As noted in MPEP § 804, a patent specification may not be used as prior art to support an obviousness-type double-patenting rejection, but may only be used as a dictionary to clarify the meaning of a term in the patent claim. The standard defined and applied in the Office Action to support the instant obviousness-type double patenting rejection is not supported either by case law or the MPEP.

The claims of the present application are directed to a pharmaceutical composition that includes four elements, namely, (1) a biopolymer; (2) a cephalosporin entrained within or ionically bound to the biopolymer; (3) a metal cation entrained within or ionically bound to the biopolymer or the cephalosporin; and (4) an absorption enhancer. The Office Action recognizes that "the '360 patent does not claim a pharmaceutical composition that comprises an adsorption [sic] enhancer"; instead, the Office Action clearly relies on several examples in the '360 patent to supply a limitation that is not recited in any claim of the '360 patent. This is an improper use of the specification as prior art to support an obvious-type double patenting rejection. Thus, Applicants respectfully request that the Examiner withdraw this rejection.

Rejection Under 35 U.S.C. §102(e)

Claims 2, 3, 5, 12, 14-16, 19 and 20 are rejected under 35 U.S.C. §102(e) "as being anticipated by Choi et al., U.S. Patent No. 6,248,360." According to the Office Action, "the claims of the patent claim similar and overlapping subject matter with the present application."

Applicants respectfully traverse this rejection. The present application is a continuation in part of the '360 patent and claims priority to the '360 patent. The disclosure of the '360 patent teaches the general concept of generic absorption enhancers. Therefore, the claims of the present application are entitled to a priority date as of the filing date of the '360 patent. Therefore, the '360 patent is not prior art with respect to the present claims.

Applicant : Choi et al.
Serial No. : 09/888,114
Filed : June 22, 2001
Page : 8 of 8

Attorney's Docket No.: 13764-007001

Thus, Applicants respectfully request that the Examiner withdraw this rejection.

Rejection Under 35 U.S.C. §103

Claims 2, 3, 5, 12 and 14-21 are rejected under 35 U.S.C. §103(a) "as being unpatentable over Choi et al., U.S. Patent No. 6,248,360 for substantially the same reasons as indicated in the double patenting rejection."

Applicants respectfully traverse this rejection. As discussed above, the claims of the present application are entitled to a priority date as of the filing date of the '360 patent.

Therefore, the '360 patent is not prior art with respect to the present claims.

Thus, Applicants respectfully request that the Examiner withdraw this rejection.

Enclosed is a \$465 check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 9/15/03

Laurie Butler Lawrence
Laurie Butler Lawrence
Reg. No. 46,593

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906